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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/732,721	12/10/2003	Alan L. Kriz	38-15(52826)B	9354

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EXAMINER	
KOROMA, BARBA M	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/732,721	KRIZ ET AL.	
	Examiner	Art Unit	
	Barba M. Koroma	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-14 and 16-18* is/are rejected.

7)☐ Claim(s) *2 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

2. Priority

The amendment to page 1, lines 2-6 of the specification is objected for containing new matter. The amendment states that the provisional application 60434242 is incorporated by reference in its entirety. This is new matter because the specification as filed only incorporated by reference the sequence list in that provisional application. See MPEP 608.01(P).

As a safeguard against the omission of a portion of a prior application for which priority is claimed under 35 U.S.C. 119(a)-(d) or (f), or for which benefit is claimed under 35 U.S.C. 119(e) or 120, applicant may include a statement at the time of filing of the later application incorporating by reference the prior application. See MPEP § 201.06(c) where domestic benefit is claimed. See MPEP § 201.13 where foreign priority is claimed. The inclusion of such an incorporation by reference statement in the later-filed application will permit applicant to include subject matter from the prior application into the later-filed application without the subject matter being considered as new matter. For the incorporation by reference to be effective as a proper safeguard, the incorporation by reference statement must be filed at the time of filing of the later-filed application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a).

3. All other objections to the specification having been corrected, are hereby withdrawn.

Claim Objections

4. The objection to claims 2 and 15 is maintained.

5. ***Claim Rejections - 35 USC 112 Second paragraph***

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation "emb5" in claims 1 and 17 render the claims indefinite. The name "emb5" is arbitrarily assigned, does not clearly identify the promoter, and does not set forth the metes and bounds of the invention, for the reasons of record stated in the Office Action mailed 9/24/04. Applicants traverse the rejection in the paper submitted October 28, 2003. Applicant's arguments were fully considered but not found persuasive.

Applicants argue that *emb5* is clearly described in the specification as filed citing page 8, lines 10-16 as follows: "EMB5 is a late embryogenesis-abundant protein and the emb5 gene is abscisic-acid responsive and expressed in maize embryos....." The argument is not found persuasive because the specification only provides expression patterns of the gene but does not differentiate the gene from other genes which may share common expression patterns.

6. New Claim Rejection:

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention. The recitation "general production or protection of next generation tissues" in lines 9 and 10, render the claims indefinite. It is not clear what is meant by 'general production', and 'protection of next generation'. General production of what, and protection from what, is not clear.

Other claim rejections set forth under 35 USC second paragraph in the First action, are hereby withdrawn.

Claim Rejections – 35 USC 112 First paragraph

7. Written description

Claims 1, 3-14, and 16-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office Action mailed 9/24/04. Applicant's traverse the rejection in the paper filed February 17, 2005. Applicant's arguments were fully considered but not found persuasive.

It appears that Applicants have responded to the written description and enablement rejections together. However, these are distinct rejections. It is requested that in future responses, Applicants separate the two because they address distinctly different issues.

Based on the language used in applicant's response, i.e. "specification as originally filed literally and fully describes a promoter," it is assumed by the examiner that the response is directed to the written description rejection.

The written description rejection to claim 14 is maintained for reciting "the 5' regulatory region of an emb5 gene" (emphasis added).

Applicant argues that the claimed about 100 to about 1650 contiguous nucleotides of DNA have from about 85% to 100% sequence identity, to at least one segment of SEQ ID No. 1 are supported in the specification as originally filed. Applicant maintains that Figure 1 of the specification describes SEQ ID No. 1 by naming its 1658 contiguous nucleotides, and that in so doing, the specification prima facie describes each and every promoter comprising from about 100 to 1650 contiguous nucleotides of SEQ ID No. 1. Applicants further argue that it would be immediately obvious to one skilled in the art that each and every nucleotide sequence comprising from about 100 to about 1650 contiguous nucleotides of SEQ ID No. 1 having embryo-specific activity is claimed (page 13, 2nd paragraph, lines 6-9).

Examiner maintains rejection based on written description because the specification does not support a description of what specific nucleotides constitute the about 100 to about 1650 nucleotides. The matter becomes even more complicated when this is viewed from the perspective of a sequence about 85% to about 100% identity with SEQ ID No. 1, while retaining embryo-specific promoter activity.

Without this crucial information, the invention as claimed is a prophetic claim. This information is also important because it help us ascertain the distinction of this emb5 promoter from another sequence that may have *emb5* promoter activity. The sequence of SEQ ID No. 1 does not describe promoter sequences from all other emb5 genes. A similar sequence representing a totally different gene segment or promoter, from a totally different species, exhibiting a totally different function, has to be distinguishable from emb5. The specification has identified a maize gene and named it "emb5" based only on its expression pattern. The specification does not describe other information about this gene, necessary to identify emb5 homologs, and therefore their promoters.

Applicant's direct attention to pages 9-10 of the specification, where it indicates that "the this invention provides derivatives of the embryo-specific promoter which has been derived from the 5' regulatory region of the maize gene, derivatives of this gene include but are not limited to deletions of sequence, single, or multiple point mutations, alterations, at a particular restriction enzyme site, addition of functional elements, or other means of molecular modification which may enhance, or otherwise alter promoter expression (response, paragraph bridging pages 13-14). However, the specification does not actually describe such promoters. A phrase like 'from about 100 to about 1650 nucleotides, and from about 85% to about 100% sequence identity to SEQ ID No. 1', does not provide adequate description to indicate that the promoter as claimed, is real and tangible.

In response to the rejection, Applicant argues that SEQ ID No. is literally and precisely described in structure and function. While this statement may be correct, derivative sequences that constitute nucleotide 1554-1658 were not taught.

Furthermore, Applicants argue that fragments including those from 5' UTR from the transcriptional start site to the ATG, are anticipate to allow functionality (response, page 14, 1st full paragraph). However, the specification does not describe a single promoter that lies within a transcript.

Applicants argue that the claims are not directed to emb5 genes, nor their function, and that a method for cloning a maize emb5 promoter is described (response, pa15, 2nd paragraph). However, again, the specification does not describe other emb5 promoters other than that of SEQ ID No. 1. This sequence does not describe the promoter of other emb5 genes. The specification doesn't describe how one skilled in the art can identify an emb5 gene. If a gene cannot be identified , it promoter cannot be identified, either. Further, a method of isolating a product does not describe the product itself.

See Fiers vs. Revel, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself".

8. Enablement

Claims 1, 3-14, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office Action mailed 9/24/04. Applicant's traverse the rejection in the paper filed February 17, 2005. Applicant's arguments were fully considered but not found persuasive.

Applicant's statement on page 15, last paragraph, that 'the specification is fully enabling of the claimed invention is incontestable as the resulting identified emb5 promoter was shown to have promoter activity in plant embryos' (emphasis added), suggests that this argument is directed at enablement.

Applicants argue that it is routine to search for other sequences homologous to the maize emb5 gene, and clone the promoters, and that this does not require knowledge of gene function (response, page 16, 1st full paragraph). However, one skilled in the art cannot confirm that a promoter belongs to a homolog of the maize emb5 gene, without knowledge of its function. Applicants also argue that the specification enables methods for detecting promoter activity, that techniques for assaying promoter activity are routine (response, page 16, 2nd full paragraph to page 17, 2nd full paragraph). However, the specification does not provide any guidance in what nucleotides of SEQ ID No. 1 may be changed, and how to change them, without abolishing

promoter function. The prior art teaches , as discussed in the previous Office Action, that even minor changes to a promoter can alter or eliminate its activity.

The rejected claims would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1st and 2nd paragraphs, set forth in this Office action.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

10. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba M. Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571 273 8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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